K080349
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MAR 10 2008

## Section 5 – 510(k) Summary

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| **Submitter:** | SIGNUS Medizintechnik GmbH<br>Carl-Zeiss-Str. 2<br>63755 Alzenau Germany |
| **Contact Person:** | Alan A. Alexander<br>Executive Vice President<br>Alquest, Inc.<br>Ph: 763-287-3830 Fax: 763-287-3836<br>ala@alquest.com |
| **Date Prepared:** | February 8, 2008 |
| **Trade Name:** | KIMBA™ mini |
| **Classification:** | Vertebral Body Replacement<br>21 CRF 888.3060 |
| **Product Code:** | MQP |
| **Predicate Device(s):** | The subject device is equivalent to the following devices:<br>KIMBA™ Spinal Implant K052533 |
| **Device Description:** | The KIMBA™ mini is a hollow, curved frame spinal implant. The upper and lower aspects of the implant are open and the upper and lower surfaces of the implant provide a surface feature which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The KIMBA™ mini implant is available in a variety of heights. This enables the surgeon to choose the size suited to the individual pathology and anatomy and condition of the patient. |
| **Intended Use:** | The KIMBA ™ mini Spinal Implant is intended for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the lumbar spine and is intended for use with supplemental internal fixation. The KIMBA ™ mini is intended to be implanted singularly.<br>The supplemental internal fixation systems that may be used with the KIMBA ™ mini spinal implant include, but are not limited to, SIGNUS Conklusion rod system, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss, TiMX, and Profile). |
| **Functional and Safety Testing:** | To verify that device design met its functional and performance requirements, representative samples of the device underwent testing in accordance with applicable industry standards or FDA guidance documents. |
| **Conclusion:** | SIGNUS GMBH considers the KIMBA™ mini to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Signus Medizintechnik GmbH
% Alquest, Incorporated
Mr. Alan Alexander
Executive Vice President
4050 Olson Memorial Highway, Suite 350
Minneapolis, MN 55422

MAR 10 2008

Re: K080349
Trade/Device Name: Kimba™ mini
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 8, 2008
Received: February 11, 2008

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Section 4 – Indications For Use Statement

**510(k) Number (if known):** ~~K TBD~~
**Device Name:** KIMBA™ mini
**Indications for Use:**

The KIMBA™ mini Spinal Implant is intended for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the lumbar spine and is intended for use with supplemental internal fixation. The KIMBA™ mini is intended to be implanted singularly.
The supplemental internal fixation systems that may be used with the KIMBA™ mini spinal implant include, but are not limited to, SIGNUS Conklusion rod system, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss, TiMX, and Profile).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark N. Milkerson

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080349